

Johnson & Johnson expands Tylenol recall

15 January 2010, By MARLEY SEAMAN , AP Health Writer

(AP) -- Johnson & Johnson expanded a recall of over-the-counter medications Friday, the second time it has done so in less than a month because of a moldy smell that has made users sick.

The broadening recall now includes some batches of regular and extra-strength Tylenol children's Tylenol, eight-hour Tylenol, Tylenol arthritis, Tylenol PM, children's Motrin, Motrin IB, Benadryl Roloids, Simply Sleep, and St. Joseph's aspirin. Caplet and geltab products sold in the Americas, the United Arab Emirates, and Fiji were recalled.

Johnson & Johnson's McNeil Consumer Healthcare Products recalled some Tylenol Arthritis Caplets in November due to the smell, which caused nausea, stomach pain, vomiting and diarrhea. Almost three weeks ago, the company expanded its recall to include [Tylenol](#) Arthritis Caplets.

The way the company handled the recall has irked federal regulators, who say McNeil did not act fast enough.

The Food and Drug Administration said McNeil knew of the problem in early 2008 but made only a limited investigation.

The agency said about 70 people were either sickened by the odor, or noticed it.

"McNeil should have acted faster," said Deborah Autor, the director of the FDA's Office of Compliance of the Center for Drug Evaluation and Research. "When something smells bad, literally or figuratively, companies must aggressively investigate and take all necessary action to solve the problem."

The FDA sent McNeil a warning letter for violating manufacturing standards and failing to report and investigate the problem in a timely way, Autor said.

Johnson & Johnson has 15 days to respond. The FDA says it wants an explanation as to why the

problem was not made public sooner.

There have been no reports of nausea related to them most recent recall, the company said.

McNeil, however, said the expanded recall includes product lots that could be affected by the same problems of nausea. A full list of the recalled products is online at <http://www.mcneilproductrecall.com>.

Johnson & Johnson says the smell is caused by small amounts of a chemical associated with the treatment of wooden pallets. The FDA said the chemical can leach into the air, and traced it to a facility in Las Piedras, Puerto Rico.

The New Brunswick, N.J., company said it is investigating the issue and will stop shipping products with the same materials on wooden pallets. It has asked suppliers to do so as well.

The company said it is working with the Food and Drug Administration.

Also on Friday, Federal prosecutors in Boston said Johnson & Johnson paid tens of millions of dollars in kickbacks so nursing homes would put more patients on its blockbuster schizophrenia drug.

The company gave special rebates to Omnicare Inc., the country's biggest company providing pharmacy services to nursing homes, in return for recommendations from its pharmacists that patients use Risperdal.

Johnson & Johnson shares fell 80 cents, or 1.2 percent, to \$64.30 Friday.

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